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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,444	03/17/2004	Eric A. Goldfarb	020489-000410US	5450

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EXAMINER

WOO, JULIAN W

ART UNIT	PAPER NUMBER
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3773

MAIL DATE	DELIVERY MODE
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11/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/803,444

Applicant(s)

GOLDFARB ET AL.

Examiner

Julian W. Woo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15 and 17-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15 and 17-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 24, 2007 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 3, 8-15, 17-27, 30, and 35-38 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuehn et al. (6,165,183). Kuehn et al. disclose, at least in figures 14A-14D and in col. 5, lines 38-41; col. 7, lines 55-59; col. 8, lines 12-30, col. 12, lines 14-17; and col. 13, lines 19-26; an interventional tool and a method with the tool for repairing a cardiac valve, where the tool and method include a catheter (126) having a shaft, a proximal portion, a distal portion, a capture device (300) detachably connected to the catheter having at least two extendable distal elements (302, 306), and at least

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two extendable proximal elements (304, 308), where the distal elements and the proximal elements are independently deployable and self-expand (by spring action) in an outward radial direction from the shaft to a deployed position and to positions between a retracted position to the deployed position (depending on the thickness of materials between the distal and proximal elements), where the at least two distal elements each have an adjustable length (i.e., distance) extending from the shaft to a tip of the at least one distal element (as the distal element is moved with respect to the distal end of the shaft), where the at least two distal elements and the at least two proximal elements are deployable by respective angular movement of the at least two distal elements and the at least two proximal element (i.e., angular movement with respect to the distal end of the shaft), so that at least two distal elements or at least two proximal elements forms an angle with the shaft (i.e. an angle between a tip of a distal element or a proximal element and the distal tip of the shaft); where the at least two proximal elements and the at least two distal elements are adapted to be adjusted angularly (with respect to the leaflets) after capturing the leaflets, where the distal portion comprises two distal elements on opposite sides of the shaft and are simultaneously deployable, where the proximal portion comprises two proximal elements on opposite sides of the shaft and are simultaneously deployable, where the at least two proximal elements and the at least two distal elements have a loop shape when deployed (see fig. 14D), where the at least two proximal elements and/or the at least two distal elements are comprised of stainless steel, where at least two distal elements and at least two proximal elements are adapted to fixedly hold the leaflets as

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captured, and where the at least two proximal elements are configured to be disposed within the edges of the corresponding at least two distal elements when both the at least two proximal elements and the at least two distal elements are in a deployed position, where the method further includes detaching the capture device from the interventional tool while the shaft is in the vasculature of the patient and retracting (pulling toward the shaft) the at least two distal elements (for engaging the distal element with a leaflet), where the at least two proximal elements are held in the retracted position under tension (i.e., by bending caused by spring force and by frictional engagement of the elements with the shaft lumen during movement of the elements within the shaft and before deployment of the elements), where deploying the at least two proximal elements comprises releasing the tension, and where tension is provided by a strand of material (326 and/or the unlabeled coil at 326) or a suture (the wire that forms 326 or the unlabeled coil), where tension is imparted to the proximal elements during pushing of the capture device through the catheter by element 326.

4. Claims 1, 6 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Marino et al. (6,206,907). Marino et al. disclose, at least in figures 7 and 9 and in col. 6 line 64 to col. 7, line 9 and col. 8, lines 37-42; an interventional tool, where the tool includes a catheter (82) having a shaft, a proximal portion, a distal portion, a capture device (80 or 110) detachably connected to the catheter having at least two distal elements (86 or 114) having first and second positions as claimed with respect to the shaft, and at least two proximal elements (90 or 118), where the proximal and distal elements are adapted to atraumatically capture the valve leaflets (at 126) and include a

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frictional accessory (e.g., 88, 92). Note: The introductory statement of intended use (“for repairing a cardiac valve of a patient having leaflets”) has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Marino et al., which is capable of being used as claimed if one desires to do so.

5. Claims 1 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Simon (4,425,908). Simon discloses, at least in figures 1-4 and 11-13 and in col. 6, lines 3-66 and col. 8, lines 24-47; an interventional tool for repairing a cardiac valve, where the tool includes a catheter (58) having a shaft, a proximal portion, a distal portion, a capture device (10) detachably connected to the catheter having at least two extendable distal elements (20), and at least two extendable proximal elements (22), where the distal elements and the proximal elements are independently deployable and self-expand in an outward radial direction from the shaft to a deployed position and to positions between a retracted position to the deployed position (depending on the thickness of materials between the distal and proximal elements), and where the at least two extendable distal elements are held in the retracted position under tension (when pulled into element 52—see fig. 12), where tension is provided by a strand of material (62) or a suture. Note: The introductory statement of intended use (“for repairing a cardiac valve of a patient having leaflets”) has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Simon, which is capable of being used as claimed if one desires to do so.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art;
2. Ascertaining the differences between the prior art and the claims at issue;
3. Resolving the level of ordinary skill in the pertinent art;
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuehn et al. Kuehn et al. disclose the invention substantially as claimed, but do not specifically disclose repositioning the capture device in relation to the leaflets and redeploying the at least one distal element and the at least one proximal element so that the valve leaflets are captured therebetween, and they do not disclose that the cardiac valve is evaluated for regurgitation. Nevertheless, Kuehn et al. teach in col. 5, lines 1-24; that surgical procedures with the interventional device are conducted under various means of visualization, and that the proximal and distal elements are actuated in order

to grasp the leaflets. It would have been obvious to one having ordinary skill in the art at the time the invention was made to reposition the capture device (before full deployment of the distal and/or proximal elements) in relation to the leaflets and redeploy the at least two distal elements and the at least two proximal elements in order to grasp the valve leaflets (which are in variable positions as the heart beats) and stabilize them at desired positions with respect to each other; and it would be obvious to evaluate (i.e., visualize) the cardiac valve for regurgitation during a surgical procedure in order to verify the effectiveness of valve-leaflet stabilization.

Response to Amendment

8. Applicant's arguments filed on July 27, 2007 have been fully considered but they are not persuasive: See the restated and new grounds of rejection above. That is, with respect to arguments regarding the rejections based on the Kuehn and Marino references: Kuehn and Marino indeed each disclose a capture device with two extendable distal elements and two extendable proximal elements; where the claims have been given their broadest reasonable interpretation; and the term "extendable" has been taken to mean that the elements are able to "occupy distance or space" (from ENCARTA World English Dictionary). Moreover, the distal elements are "independently deployable" from the proximal elements.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-

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4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

November 16, 2007